FDA. It enjoys broad bipartisan congressional support, and the full support of the administration. I urge quick passage today of the Animal Drug Availability Act. Thank you; I yield back the balance of my time.

Mr. BLILEY. Mr. Speaker, we now take up a bill that is important to protect animal health at home and on the farm. The animal health industry keeps our pets healthy—including some 130 million dogs and cats—and agricultural animals that are vital to our food supply. The animal health industry protects human health by safeguarding the health of food and domestic animals.

I have heard repeated concern from Members on both sides of the aisle that our FDA system for reviewing animal drug products needs significant improvement. Their concern reflects the frustration of diverse groups including agricultural interests, the animal drug industry, veterinarians, and animal producer groups.

Our arsenal of drugs to fight animal disease is not growing.

The FDA review process for animal drugs is much too slow—instead of 6 months, the process has averaged up to 5 years.

Some industry has become discouraged and divested animal drug development capability.

Mr. ALLARD, Mr. GANSKE, Mr. KLUG, have been among those who said that it's time to take action and make changes. I particularly want to thank Mr. GANSKE who has come from his hospital bed to be here today to demonstrate his support. Even the administration recognized the need to reform to streamline animal drug regulation and made its own proposals that were consistent with our views.

The committee considered animal drug regulations as part of a broader initiative to streamline FDA regulation. We have made significant progress and I am very pleased that today we take up the completed animal drug reforms in H.R. 2508.

The committee efforts have been helped by collaboration from the administration, the animal health coalition, veterinarians, and others interested in safeguarding our animals. I would like to thank each of them and their dedicated staff for their hard work.

H.R. 2508 will facilitate the approval and marketing of new animal drugs and medicated feeds. It builds needed flexibility into the FDA animal drug review processes to enable more efficient approval and more expeditious marketing of safe and effective animal drugs.

H.R. 2508 accomplishes streamlines without decreasing FDA's existing authority to ensure that animal drug products are safe for the animals that use them and for the humans who consume animal food products.

Our reforms are sensible, pragmatic, and above all else, protective of public health. Of this accomplishment, I believe we can rightly be proud.

Mr. STENHOLM. Mr. Speaker, H.R. 2508 is an example of how serious reform can and should occur. The Animal Drug Availability Act of 1995 enjoys broad support from camps that do not always see things from the same viewpoint, however, both the FDA and the regulated community agree on the reform embodied in H.R. 2508. Additionally, the users of animal drugs, the veterinarians, and the various animal agriculture groups representing farmers and ranchers that raise beef, pork, and poultry all support this bill. The Animal Drug Availability Act represents what can be accomplished when all involved, regulators, those regulated, and the end users sit down and sincerely listen to each other. Unfortunately, the larger issue of FDA reform has been slowed for a variety of reasons. Hopefully, this bill should serve as an example of how future Congresses can approach larger FDA reform and of the progress that can result from bipartisan discussion open to all stakeholders.

H.R. 2508, the Animal Drug Availability Act of 1995, represents common sense reform that reduces regulatory hurdles for efficacy testing and preserves safety testing. Let me say that again. The Animal Drug Availability Act does not reduce evaluation of products on the basis of human safety, nor does it reduce the FDA's ability to require target animal safety information. Essential safety standards for humans and animals would not be weakened in any way. The effect of the reform should be a speedier approval process without jeopardizing safety confidence.

Animal health products many times do not command lucrative markets and it is difficult to justify investment into research and development for a new product or an additional approved use on a label if markets are limited or absent. Currently a large commitment in time and money is required to prove a product's efficacy claims. This bill would give the FDA greater flexibility in determining the type and number of studies it can accept as proof of an animal drug's efficacy. Streamlining the process and eliminating unnecessary field trials should speed the time to an approval decision and hopefully reduce some negative economic pressures being applied by the regulatory system.

Small markets or limited economic incentives, do not mean that drugs for animals are not important. Take for instance the cattleman who has experienced difficult times with low cattle prices who may be trying to diversify and is starting to raise ostriches or pheasants, or a farmer who is involved in aquaculture, or even the wildlife or zoo veterinarian who deals with very unique patients. These are examples of animals that as a species represent few in number and generate very little economic incentive for a drug manufacturer to pursue R&D in that area . . .the so-called minor use/minor species problem of animal drugs. The legislation that legalized extra label drug use in animals by veterinarians was sponsored by this Member and others in the last Congress—the Animal Medicinal Drug Clarification Act of 1994. Extra label drug use will always be necessary, however, this bill will potentially help reduce the reliance on using drugs extra label. It can offer an opportunity for FDA to evaluate how the Animal Medicinal Drug Use Clarification Act and the Animal Drug Availability Act could efficiently work together.

It is with some pride, as sponsor of the legislation that dealt with extra label use of animal drugs and now as one of the original cosponsors of the Animal Drug Availability Act, that this House is here addressing this issue on the Suspension Calendar. I am proud that animal drug regulatory reform may very well become an example of how larger FDA regulatory reform can be accomplished. I ask my colleagues to support H.R. 2508 and encourage the Senate to act quickly so that the President can sign this appropriate reform into law.

Mr. ROBERTS. Mr. Speaker, I rise in strong support of this legislation which is vital to the future health of the Nation's livestock and poultry industry in rural districts throughout this country. H.R. 2508, the Animal Drug Availability Act, is a noncontroversial, bipartisan bill that streamlines and significantly improves the process by which animal drugs are approved. The bill expands the types of studies FDA can accept as proof of a drug's efficacy; requires FDA and drug companies to agree to test protocols before a company submits a drug application for approval; eliminates time-consuming field investigations, unless they are the only way to prove a drug's efficacy; eliminates some efficacy testing when a company seeks to use two individually approved drugs in combination; creates veterinary feed directive drugs which increase veterinarian involvement in dispensing animal drugs; and eliminates much of the licensing paperwork for feed mills that dispense animal drugs.

The bottom line: this bill is perhaps the most significant thing this Congress can do to help the livestock and poultry industry reduce their cost of production and become more competitive.

The cumbersome and lengthy process of getting animal drug approvals from FDA has led to several U.S. animal drug companies setting up plants overseas. Passage of this bill will also help stem the flow of jobs—well paying jobs—from this country.

I am pleased to finally get a chance to discuss and vote on this important piece of legislation and I would strongly urge my colleagues to vote in favor of its passage.

Mr. MANTON. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

Mr. BILIRAKIS. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Florida [Mr. BILIRAKIS] that the House suspend the rules and pass the bill, H.R. 2508, as amended.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

GENERAL LEAVE

Mr. BILIRAKIS. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks on H.R. 2508.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Florida?

There was no objection.

CONFERENCE REPORT ON H.R. 2202, ILLEGAL IMMIGRATION REFORM AND IMMIGRANT RESPONSIBILITY ACT OF 1996

Mr. SMITH of Texas submitted the following conference report and statement on the bill (H.R. 2202) to amend the Immigration and Nationality Act